

Authorization is hereby given to charge Deposit Account No. 23-1703 in the amount of Nine Hundred and Thirty Dollars (\$930.00) to cover the extension fee as required by 37 C.F.R. §1.17(a)(3) and 1.136(a).

Submitted concurrently herewith is a Terminal Disclaimer pursuant to 37 C.F.R. §1.321(c) to obviate an obviousness-type double patenting rejection of record.

IN THE CLAIMS:

Substitute pending claim 1 with the following amended claims 1:

1. (Amended) Magnesium salt of (-)-5-methoxy-2-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-H-benzimidazole.

REMARKS

1. Claim rejection- 35 U.S.C. §112

Claim 1 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has indicated that the term "comprising" is improper in a compound claim.

Claim 1 has been amended by the deletion of the term "comprising". Applicants submit that the term "comprising" was deleted, as suggested by the Examiner, to put the claim in proper form for claiming a compound. The deletion of the term "comprising" is not intended, therefore, to limit the scope of compounds encompassed by the claimed invention.

II. Claim Rejection – Obviousness-type Double Patenting

Claims 1 and 35 are presently under examination. Claims 8, 9 and 36-42 are withdrawn from consideration.

On page 2 of the Office Action, it is stated that:

Claims 1 and 35 are again rejected under the judicially created doctrine of obviousness-type double patenting over patent 4,738,974 and 5,877,192. The T.D. submitted by applicant is improper because the serial number of the application is incorrect. (Emphasis added).

Applicants respectfully submit that the identification of US 4,738,974 in the preceding paragraph from the Office Action is incorrect. Applicants submitted a Terminal Disclaimer with respect to US 5,714,504 and US 5,877,192. Applicants rely on their arguments of record, as set forth in the Amendment filed May 29, 2002, that an obviousness-type double patenting rejection with respect to US 4,738,974 would be improper.

Submitted concurrently herewith is a new Terminal Disclaimer overcoming the obviousness-type double patenting rejection in connection with US 5,714,504 and US 5,877,192. Withdrawal of the rejection is requested.

III. Claim Rejections – US 6,369,085

a) 35 U.S.C. §101

Claims 1 and 35 are rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-3 of commonly owned US 6,369,085 (the '085 patent). Applicants submit that the statutory double patenting rejection under 35 U.S.C. §101 is improper for the following reasons.

Firstly, the earliest effective prior art date of the '085 patent is its §102(e) date, i.e., May 25, 1998. The '085 patent issued April 9, 2002. In contrast, the referenced application is

entitled to a Swedish priority date of May 28, 1993. Therefore, '085 patent does not qualify as prior art vis-à-vis the claimed invention.

Secondly, claims 1 and 35 of the referenced application and claims 1-3 of the '085 patent do not claim the same invention. As such, the scope of the respective inventions is not identical. In this regard, the Examiner's attention is directed to the M.P.E.P. §804(II)(A) at 800-20 and 22.

Therefore, withdrawal of the §101 rejection is requested.

b) 35 U.S.C. §102 (g) and possibly 35 U.S.C. §(f)

Claims 1 and 35 are alleged to be directed to the same invention as that of claims 1-3 of the commonly assigned '085 patent. The Examiner states that the alleged issue of priority under 35 U.S.C. §102(g) and possibly (f) of this single invention must be resolved. Applicants are required to state which entity is the prior inventor of the alleged conflicting subject matter.

Applicants rely on the arguments in Sections III(a), above. Claims 1 and 35 of the referenced application and claims 1-3 of the '085 patent do not claim the same invention. As such, the scope of the respective inventions is not identical.

c) Obviousness-type Double Patenting

Claims 1 and 35 are rejected under the judicially created doctrine of obviousness-type double patenting over the '085 patent.

An obviousness-type double patenting rejection is appropriate when any claim in the application defines an invention that is *merely an obvious variation* of an invention claimed in the patent. An obviousness-type double patenting rejection is analogous to the nonobviousness requirement of 35 U.S.C. §103. As such, the analysis employed in an obviousness-type double

patenting determination must be based on the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q.4589 (1966). Therefore, the Examiner is required to consider any objective indicia of nonobviousness, such as unexpected results. In this regard, the Examiner's attention is directed to M.P.E.P. §804(II)(B) at 800-22.

The '085 patent discloses and claims the magnesium salt of S-omeprazole trihydrate. The expression "S-omeprazole" is interchangeable with "the (-)-enantiomer of omeprazole". *The compounds of the '085 patent, i.e., the magnesium salt of S-omeprazole trihydrate, is substantially free from magnesium salts of R-omeprazole and other forms of the magnesium salt of S-omeprazole (See the '085 patent at col. 2, lines 30-37).* The magnesium salt of S-omeprazole trihydrate of the '085 patent is uniquely characterized by an X-ray powder diffractogram (See claim 1). Moreover, it was demonstrated with data comparative submitted during the examination of the application underlying the '085 patent, that the magnesium salt of S-omeprazole trihydrate is more stable after 6 and 12 months than the prior art magnesium salt of S-omeprazole dihydrate.

Applicants submit that the improved stability of the compounds of the '085 is evidence that the difference between the claimed subject matter of the subject application and the '085 patent, respectively, is more than just an obvious variation.

Withdrawal of the obviousness-type double patenting rejection is requested.

Mark-up of amended claim 1:

1. Magnesium [An optically pure compound comprising a magnesium] salt of (-)-5-methoxy-2-
[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-H-benzimidazole.

CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. Claims 1 and 35 are directed to patentable subject matter. Accordingly, Applicants request reconsideration and allowance of the claims.

Any additional fee due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: 30 January 2003

Respectfully submitted,



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